K082426

510(k) Summary

SEP - 5 2008

General Information

Submitters Name/Address:	Smith & Nephew, Inc 970 Lake Carillon Drive Suite 110 St. Petersburg, FL 33716
Establishment Registration Number:	1017593
Contact Person:	Laura Krejci – Regulatory Affairs Manager
Phone Number:	(727) 329-7702
Date Prepared:	August 20th, 2008

Device Description

Trade Name:	Renasys™ EZ Negative Pressure Wound Therapy
Generic/Common Name:	Suction Pump and Accessories
Classification Name:	Powered Suction Pump; 21 CFR 878.4780 Product Code; BTA

Predicate Device Information

Versatile 1™EZCare Wound Vacuum System cleared originally in k061919.

Product Description

The Renasys EZ is a powered suction pump with accessory wound dressing kits, disposable canister and filter designed for Negative Pressure Wound Therapy (NPWT). The Renasys EZ is designed for use with various Smith & Nephew wound dressing kits to deliver a recommended therapeutic range of 40-80 mmHg of continuous or intermittent topical negative pressure to a wound site for the purposes of wound healing.

Intended Use

Renasys EZ is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

Summary of Safety and Effectiveness

In establishing substantial equivalence to the current marketed devices, Smith & Nephew, Inc evaluated the indications for use, materials, technology, product specifications and energy requirements of the current marketed device. The device comparison demonstrated that the Renasys EZ is substantially equivalent to the marketed device and is safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Smith & Nephew, Inc.
% Ms. Laura Krejci
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K082426
Trade/Device Name: Renasys EZ
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 20, 2008
Received: August 22, 2008

Dear Ms. Krejci:

This letter corrects our substantially equivalent letter of September 5, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (unknown): K082426

Device Name: RENASYS EZ

Indications for Use:

The Renasys EZ is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082426